IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
Civil Action No. 1:25-CV-00299

Liquidia Technologies, Inc., Plaintiff, v. United Therapeutics Corporation, Defendant.	**COMPLAINT** **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Liquidia Technologies, Inc. ("Liquidia"), by its undersigned attorneys, hereby files this complaint for patent infringement against Defendant United Therapeutics Corporation ("UTC"), and hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for the infringement of United States Patent No. 10,898,494 (the "'494 patent") under the patent laws of the United States, Title 35, United States Code, §§ 100, *et seq.*, including § 271 (b)-(c), arising from UTC's unauthorized development, manufacturing, commercial marketing, distribution, offers for sale, sales and/or use of TYVASO DPI® (treprostinil) inhalation powder for the treatment of pulmonary arterial hypertension ("PAH") and pulmonary hypertension associated with interstitial lung disease ("PH-ILD"), as detailed herein. A true and accurate copy of the '494 patent is attached to this complaint as **Exhibit A**.

THE PARTIES

2. Plaintiff is a biopharmaceutical company focused on the development and commercialization of treatments for pulmonary hypertension ("PH") and other applications of its proprietary PRINT drug development technology. It is incorporated under the laws of Delaware, with its principal place of business at 419 Davis Drive, Suite 100, Morrisville, North Carolina 27560.

3. On information and belief, UTC is a corporation organized and existing under the laws of the State of Delaware and having its principal place of business and co-corporate headquarters at 55 T.W. Alexander Drive, Research Triangle Park, North Carolina 27709.

JURISDICTION AND VENUE

4. This is a civil action arising under the Patent Laws of the United States, 35 U.S.C. § 100 *et. seq.*, including § 271 (b)-(c). This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338.

5. This Court has personal jurisdiction over UTC.

6. This Court has personal jurisdiction over UTC because it maintains its corporate headquarters and principal place of business in North Carolina.

7. This Court also has personal jurisdiction over UTC because, upon information and belief, UTC is engaged in developing, manufacturing, marketing, selling, and distributing pharmaceutical products, including TYVASO DPI® throughout the United States, including in North Carolina.

8. This Court also has personal jurisdiction over UTC because there is a direct connection between the Liquidia's patent infringement claims and UTC's significant presence and directly related activities in North Carolina, which give rise to Liquidia's patent infringement claims.

9. This Court also has personal jurisdiction over UTC because it has availed itself of the legal protections of the State of North Carolina by, among other things, establishing its co-headquarters in the state and consenting to jurisdiction by participating in lawsuits and/or filing complaints in lawsuits that are filed in this Court. *See United Therapeutics Corp. v. Liquidia Techs., Inc.*, C.A. No. 1:22-cv-00007-UA-JLW (M.D.N.C.); *United Therapeutics Corp. v. Vanderbilt University*, C.A. No. 1:17-cv-00753-UA-LPA (M.D.N.C.).

10. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b) because UTC resides in this District, including by maintaining its corporate headquarters in this district and because UTC conducts business within this District, including, upon information and belief, a substantial part of the events that give rise to Liquidia's patent infringement claims.

FACTUAL BACKGROUND

I. TREATMENT OF PAH AND PH-ILD WITH TREPROSTINIL

11. PAH is a rare, chronic, progressive disease caused by hardening and narrowing of the pulmonary arteries that can lead to right heart failure and eventually death.

12. Currently, an estimated 45,000 patients in the United States are diagnosed

with and receiving treatment for PAH.

13. There is currently no cure for PAH, so the goals of existing treatments are to alleviate symptoms, maintain or improve functional class, delay disease progression, and improve quality of life.

14. PH-ILD includes a diverse collection of up to 150 different pulmonary diseases, including interstitial pulmonary fibrosis, chronic hypersensitivity pneumonitis, connective tissue disease-related ILD, and chronic pulmonary fibrosis with emphysema among others.

15. A current estimate of PH-ILD prevalence in the United States varies by source but is believed to be at least 60,000 patients.

16. As with PAH, there is currently no cure for PH-ILD, so the goals of existing treatments are to alleviate symptoms, maintain or improve functional class, delay disease progression, and improve quality of life.

17. Treprostinil is approved by the FDA for the treatment of PAH via infusion, oral, and inhaled administration routes. Treprostinil is approved by the FDA for the treatment of PH-ILD via inhalation.

II. THE ASSERTED PATENT

A. U.S. Patent No. 10,898,494

18. The ’494 patent, entitled “Dry powder treprostinil for the treatment of pulmonary hypertension,” issued on January 26, 2021, naming Robert Frank Roscigno, Brian T. Farrer, Jacob J. Sprague, and Benjamin Maynor as the inventors. The ’494 patent

currently expires on May 5, 2037.

19. Liquidia owns by assignment the entire right, title, and interest in and to the '494 patent.

20. The '494 patent describes, *inter alia*, a method for treating pulmonary hypertension by administering from about 100 to 300 micrograms of a dry powder composition of treprostinil or a pharmaceutically acceptable salt, via a dry powder inhaler. The administration occurs over one to four breaths. *See generally* Exhibit A.

21. Claim 1 of the '494 patent recites:

> "[a] method for treating a patient, comprising administration of a dry powder composition comprising from about 100 micrograms to about 300 micrograms treprostinil or a pharmaceutically acceptable salt thereof to a patient by inhalation using a dry powder inhaler over one to four breaths to treat pulmonary hypertension."

III. TYVASO DPI®

22. Upon information and belief, UTC is the owner of NDA No. 214324 for TYVASO DPI® (treprostinil) inhalation powder which was approved by the U.S. Food and Drug Administration ("FDA") on May 23, 2022.

23. According to the TYVASO DPI® (treprostinil) Prescribing Information (hereinafter "Prescribing Information") it is indicated "for the treatment of pulmonary arterial hypertension (PAH; WHO Group I) to improve exercise ability" and "the treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability." A true and accurate copy of the Prescribing Information is attached hereto as **Exhibit B**.

24. TYVASO DPI® (treprostinil) is an inhalation dry powder formulation with an active ingredient of treprostinil. *See e.g.*, Exhibit B at §§ 1-3, 11, 16.

25. Upon information and belief, UTC currently markets and sells TYVASO DPI® (treprostinil) inhalation powder.

26. The TYVASO DPI® (treprostinil) Prescribing Information discloses that it is available in various kits of TYVASO DPI® (treprostinil) inhalation powder, including TYVASO DPI® (treprostinil) Inhalation Powder Titration Kits, TYVASO DPI® (treprostinil) Inhalation Powder Maintenance Kits, and TYVASO DPI® (treprostinil) Inhalation Powder Institutional Kits. Exhibit B at §16. TYVASO DPI® (treprostinil) is supplied in single-dose plastic cartridges filled with a white powder containing 1% treprostinil and a prostacyclin mimetic, which is intended for administration using only the TYVASO DPI® Inhaler. Exhibit B at § 11.1.

27. The Prescribing Information further discloses that TYVASO DPI® (treprostinil) is available in single-dose plastic cartridges containing 16 mcg, 32 mcg, 48 mcg, 64 mcg, or 80 mcg of treprostinil. Exhibit B at §§ 3, 11.1, 16. The Prescribing Information directs that if a patient is prescribed a dose exceeding 80 mcg per treatment session, the patient must use more than one cartridge per session. *See* Exhibit B at § 2.1.

28. According to the Prescribing Information, TYVASO DPI® (treprostinil) is administered via one or more single inhalation cartridges, administered in four separate, equally spaced treatment sessions per day, approximately four hours apart. Exhibit B § 2.1.

29. According to the Prescribing Information, UTC provides TYVASO DPI® (treprostinil) in kit configurations, including, for example:

- Maintenance kit NDC 66302-640-03, which contains 112 cartridges of 48 mcg per cartridge, 112 cartridges of 64 mcg per cartridge, and 5 inhalers to administer the inhalation powder. Exhibit B at § 16.
- Maintenance kit NDC 66302-650-03, which contains 112 cartridges of 16 mcg per cartridge, 112 cartridges of 48 mcg per cartridge, 112 cartridges of 64 mcg per cartridge, and 5 inhalers to administer the inhalation powder. *Id.*

30. Upon information and belief, patients who are prescribed maintenance kit NDC 66302-640-03 are instructed to use one 48 mcg cartridge and one 64 mcg cartridge, administering a total of 112 mcg of treprostinil, at each treatment session.

31. Upon information and belief, patients who are prescribed maintenance kit NDC 66302-650-03 are instructed to use one 16 mcg cartridge, one 48 mcg cartridge and one 64 mcg cartridge, administering a total of 128 mcg of treprostinil, at each treatment session.

32. Upon information and belief, each kit contains a 28-day supply of TYVASO DPI® (treprostinil); the 112 cartridges of the respective dosages are intended to be consumed one per treatment session, with 4 treatment sessions per day over the 28-day period.

33. The TYVASO DPI® (treprostinil) Instructions for Use (hereinafter "Instructions for Use"), which are attached hereto as **Exhibit C**, indicates that TYVASO

DPI cartridges come in 5 strengths. *See* Exhibit C at 2.

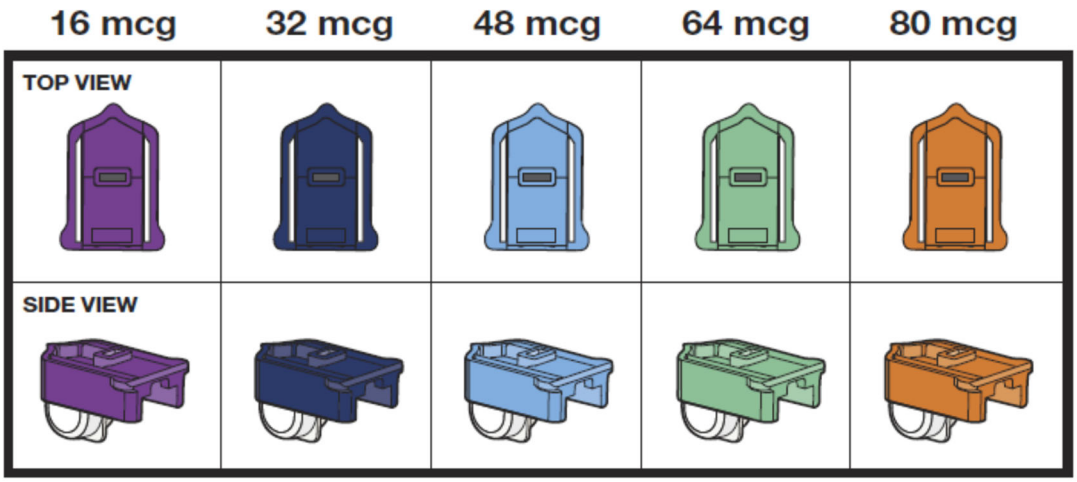


Figure D

34. The Instructions for Use direct patients prescribed a dose exceeding 80 mcg per treatment session to use multiple cartridges per session. *See* Exhibit C at 2 ("If your prescribed dose is higher than 80 mcg per treatment session, you will need to use more than 1 cartridge…. the cartridges can be used in any order, regardless of cartridge strength."). Upon information and belief, UTC instructs and promotes the use of TYVASO DPI® in single administration doses equal to or higher than 100 mcg. The Instructions for Use includes figures demonstrating how patients must combine cartridges to achieve higher than 80 mcg prescribed dosages.

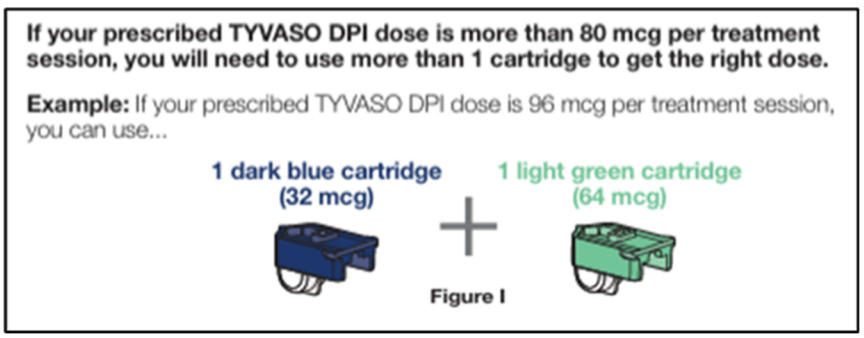


Figure I

Id. at 4.

If your dose requires you to inhale multiple cartridges, **repeat steps 6 through 9** for each cartridge.

Example: If your prescribed TYVASO DPI dose is 96 mcg per treatment session, you can use one 32 mcg cartridge and one 64 mcg cartridge (see **Figure AF**):

Figure AF

Id. at 12.

35. The Instructions for Use include figures demonstrating how patients should inhale the single-use cartridges in one breath and discard the cartridge after use. *See generally id.* at 8-10.

Before inhaling TYVASO DPI, fully review all parts of Step 7 before you take your dose.

Step 7: Inhale Your Dose

Remove the Mouthpiece Cover (see **Figure T**).

Important: Keep the inhaler level during and after removal of the blue mouthpiece cover to prevent loss of TYVASO DPI powder.

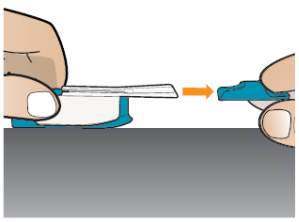


Figure T

Hold Inhaler Near Cheek

While keeping the inhaler level, carefully pick up the inhaler and bring it near your cheek, but not in front of your mouth (see **Figure U**).

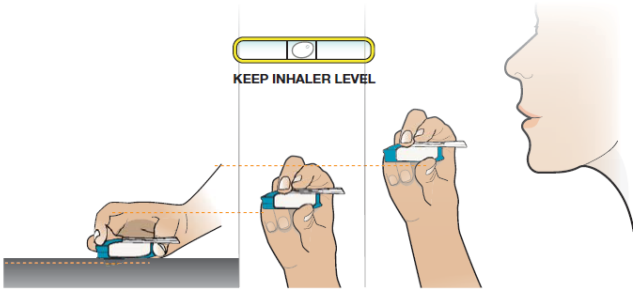


Figure U

Exhale

Holding the inhaler away from your mouth, fully blow out (exhale) (see **Figure V**).

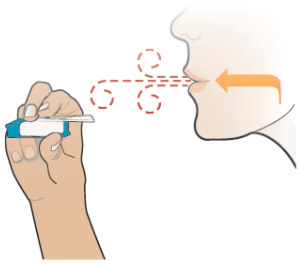
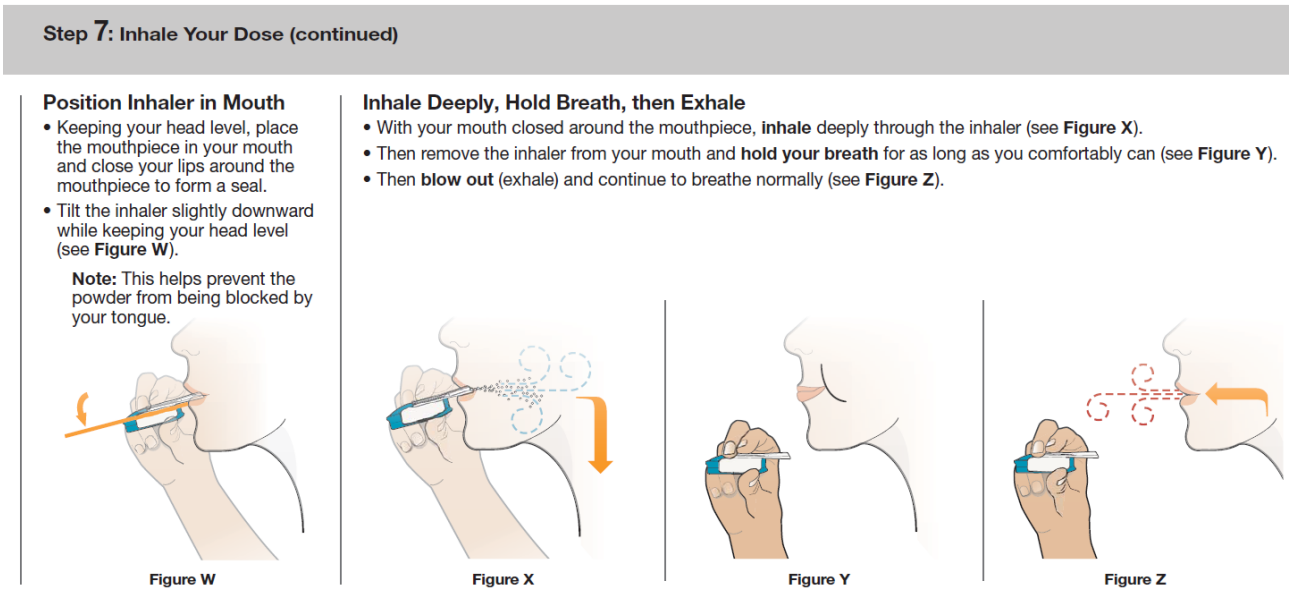
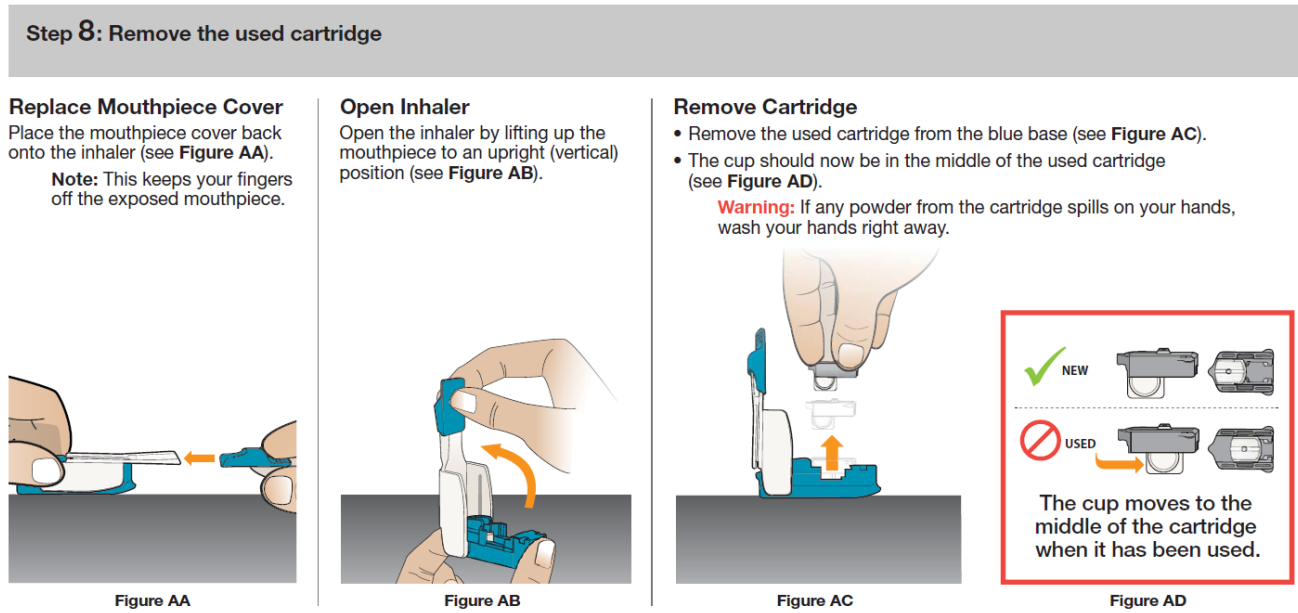


Figure V

Id. at 8.



Id. at 9.



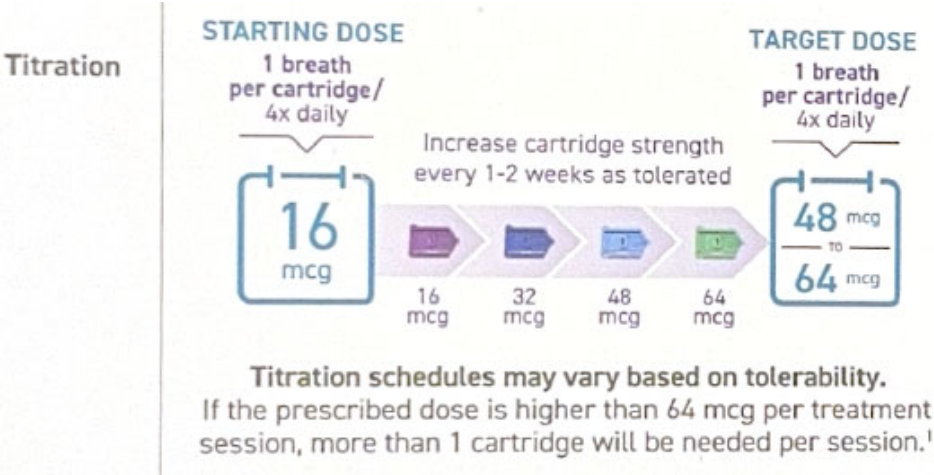
Id. at 10.

36. Upon information and belief, UTC markets, promotes and instructs for the use of TYVASO DPI® (treprostinil) in single administration doses equal to or higher than 100 mcg. For example, UTC's "Choosing the Best TYVASO Device for Your Patients"

brochure (hereinafter the "TYVASO Brochure") is a marketing material distributed to attendees of the American College of Cardiology conference held on March 29-31, 2025, and is also publicly available through a QR code located on the last page of the brochure. A true and correct copy of the TYVASO Brochure is attached hereto as **Exhibit D**.

37. The TYVASO Brochure is directed at prescribers and presents a comparison between the two TYVASO products: TYVASO DPI® (treprostinil) inhalation powder and TYVASO® (treprostinil) inhalation solution for use with a nebulizer.

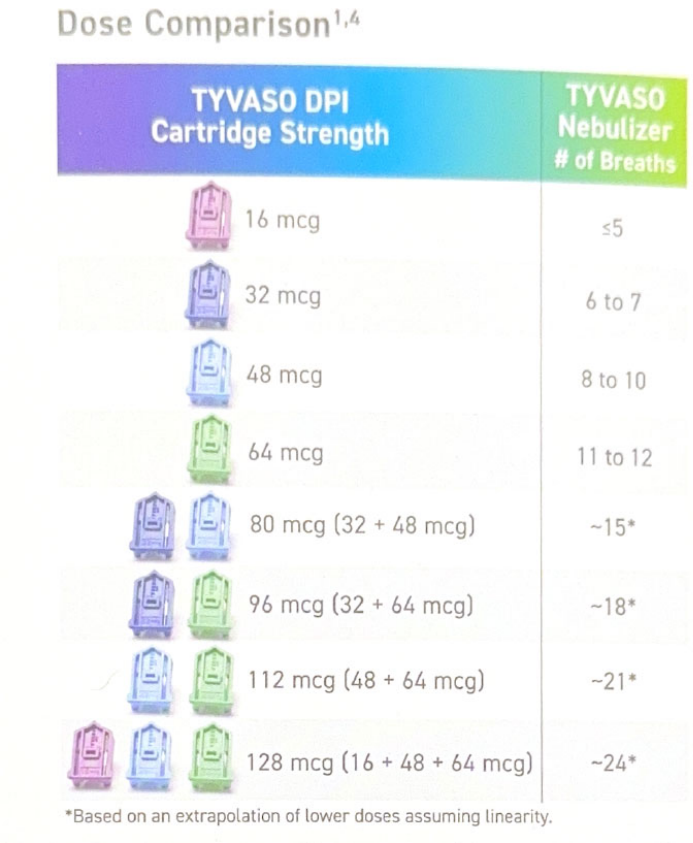
38. According to the TYVASO Brochure, patients are instructed to administer each TYVASO DPI® (treprostinil) cartridge in a single breath in four treatment sessions daily. *See* Exhibit D. The TYVASO Brochure states that prescribed doses exceeding 64 mcg per treatment session require the use of more than one cartridge per session. *See id.*



Id.

39. Upon information and belief, UTC's TYVASO Brochure instructs and promotes the use of TYVASO DPI® (treprostinil) in single administration doses equal to or exceeding 100 mcg. For example, the dose comparison chart within the TYVASO

Brochure indicates that, to achieve a 112 mcg dose, one 48 mcg cartridge and one 64 mcg cartridge should be inhaled during a single session. *See* Exhibit D. To achieve a 128 mcg dose, one 16 mcg cartridge, one 48 mcg cartridge, and one 64 mcg cartridge should be inhaled in a single session. *Id.*



Id.

40. UTC identifies reference materials in the TYVASO Brochure and provides the necessary citations with the intent that healthcare professionals review the referenced material. For example, in the section "Dose Comparison," UTC identifies in footnote 4 the article titled "Tyvaso DPI: Drug-Device Characteristics and Patient Clinical Considerations" authored by McEvoy et al. (hereinafter "McEvoy 2023"). *See* Exhibit D

(Dose Comparison). A true and correct copy of McEvoy 2023 is attached hereto as **Exhibit E**. The development of McEvoy 2023 was financially supported by UTC. *See* Exhibit E at 7 (Funding). At least four of the listed named authors are employees of UTC. *See id.* at 1, 7 (Declaration of Competing Interest). Additionally, several of the named authors have received compensation from UTC and/or participated in UTC advisory boards and clinical trials. *Id.*

41. The cited McEvoy 2023 reference discloses TYVASO DPI® (treprostinil) "utilizes single-use, prefilled cartridges, allowing for dosing to be achieved with one breath per cartridge." Exhibit E at 3. Table 2 of McEvoy 2023 discloses TYVASO DPI® (treprostinil) dosages ranging from 16 mcg to 176 mcg, including doses of 112 mcg, 128 mcg, 144 mcg, 160 mcg, and 176 mcg, and that "higher strength cartridges are currently under development.". *See* Exhibit E at 3 (Table 2). Table 2 indicates that doses of 80 mcg or higher require the use of two or more cartridges. *See id.*

Table 2
Comparison of Tyvaso DPI and Approximate Tyvaso nebulizer dosages [10].

Tyvaso DPI Cartridge Strength[a]	Tyvaso Nebulizer Number of Breaths
16 μg	≤5 (≤30 μg)
32 μg	6 to 7 (36–42 μg)
48 μg	8 to 10 (48–60 μg)
64 μg	11 to 13 (66–72 μg)
80 μg	14 to 16 (78–90 μg)
96 μg	17 to 19 (96–112 μg)
112 μg	20 to 22 (118–130 μg)
128 μg	23 to 25 (136–148 μg)
144 μg	26 to 28 (154–166 μg)
160 μg	29 to 31 (172–184 μg)
176 μg	32 to 34 (190–202 μg)

[a] Doses of ≥80 μg requires the use of ≥2 cartridges.

Id.

42. With respect to the "Efficacy" of TYVASO DPI® at doses higher than 100 mcg, McEvoy 2023 discloses the results of an open-label safety and tolerability study of TYVASO DPI® (treprostinil), the BREEZE study, in which six of the enrolled patients achieved dosages at or above 112 mcg, and one patient who reached a dosage of 176 mcg after a mean treatment duration of 51 weeks. *See* Exhibit E at 5-6.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 10,898,494
(UNDER 35 U.S.C. § 271(b) – (c))

43. Liquidia hereby realleges and incorporates by reference the allegations of paragraphs 1-42 of this Complaint as though fully set forth herein.

44. Claim 1 of the '494 patent recites:

> "[a] method for treating a patient, comprising administration of a dry powder composition comprising from about 100 micrograms to about 300 micrograms treprostinil or a pharmaceutically acceptable salt thereof to a patient by inhalation using a dry powder inhaler over one to four breaths to treat pulmonary hypertension."

45. Upon information and belief, UTC engages in the manufacture, use, offer for sale, sale, marketing, and/or distribution of UTC's TYVASO DPI® (treprostinil) product and labeling prior to the expiration of the '494 patent.

46. The active ingredient in UTC's TYVASO DPI® (treprostinil) product is treprostinil. Upon information and belief, the TYVASO DPI® (treprostinil) product, and its use in accordance with and as directed by UTC's Prescribing Information, Instructions for Use for that product, and the TYVASO Brochure, has and will continue to literally infringe one or more claims of the '494 patent.

47. Upon information and belief, UTC promotes, suggests and instructs for the use of the TYVASO DPI® (treprostinil) product in dosages of 100 mcg or more per treatment session.

48. For example, when used according to the Prescribing Information, Instructions for Use, and TYVASO Brochure, patients prescribed Kit NDC 66302-640-03 will consume a 48 mcg cartridge in one breath and a 64 mcg cartridge in another breath for a total of 112 mcg of treprostinil per treatment session, requiring two inhalations per session. Similarly, patients prescribed Kit NDC 66302-650-03 will consume a 16 mcg cartridge in one breath, a 48 mcg cartridge in one breath, and a 64 mcg cartridge in a third breath for a total of 128 mcg of treprostinil per treatment session, requiring three inhalations per session. Accordingly, at least physicians and healthcare providers who prescribe and administer, and patients who use the Kit NDC 66302-640-03 and/or Kit NDC 66302-650-03 as directed by the Prescribing Information, Instructions for Use, and TYVASO Brochure will directly infringe at least claim 1 of the ’494 patent.

49. Upon information and belief, UTC actively induces infringement of the ’494 patent, including at least claim 1, under 35 U.S.C. § 271(b). UTC has had knowledge of the ’494 patent and, with the specific intent to encourage infringement, instructs patients, physicians, and healthcare providers to use the TYVASO DPI® (treprostinil) product in dosages at or above 100 mcg per treatment session. For example, this includes the use of Kit NDC 66302-640-03 and Kit NDC 66302-650-03, in a manner that infringes the ’494 patent. The Prescribing Information, Instructions for Use, TYVASO Brochure and

McEvoy 2023 direct the use of specific cartridge combinations and inhalation regimens that result in the infringement of at least claim 1 of the ’494 patent.

50. Upon information and belief, UTC contributorily infringes at least claim 1 of the ’494 patent under 35 U.S.C. § 271(c) by manufacturing, offering to sell, and selling TYVASO DPI® (treprostinil) for use in treatment sessions requiring dosages of 100 mcg or more per session, including Kit NDC 66302-640-03 and Kit NDC 66302-650-03, which are not suitable for any substantial noninfringing use.

51. Upon information and belief, UTC knowingly and intentionally instructs physicians, health care providers, and/or patients to use the TYVASO DPI® (treprostinil) product in accordance with the instructions and/or label provided by the ’494 patent with the requisite intent and/or knowledge under 35 U.S.C. § 271(b) and (c).

52. The foregoing actions by UTC constitute infringement of the ’494 patent, including active inducement of infringement of the ’494 patent and contribution to the infringement by others of the ’494 patent.

53. UTC’s actions constitute infringement the ’494 patent, including actively inducing infringement of the ’494 patent and contributing to the infringement of the ’494 patent by others. As a result of UTC’s actions, Liquidia has suffered harm and is entitled to recover damages in accordance with 35 U.S.C. §§ 271, 281, and 284.

54. Upon information and belief, UTC has acted without a reasonable basis for believing that it would not be liable for infringement of the ’494 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully request the following relief:

A. A judgment that UTC has and will infringe either literally, or under the doctrine of equivalents, actively induce infringement of, and/or contribute to the infringement by others at least one claim of the ’494 patent under 35 U.S.C. §§ 271(b)–(c);

B. That Liquidia be awarded damages adequate to compensate it for UTC’s past, present, and/or future infringement of the ’494 patent, said damages being no less than a reasonable royalty and/or lost profits together with any pre-judgment and post-judgment interest as allowed by law, costs, and other damages permitted by 35 U.S.C. § 284;

C. An award of attorneys’ fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

D. An award of costs and expenses in this action; and

E. Such other relief as the Court deems just and proper.

Dated: April 21, 2025

/s/*Stephen V. Carey*

PARKER POE ADAMS & BERNSTEIN LLP
Stephen V. Carey (N.C. Bar No. 52791)
Corri A. Hopkins (N.C. Bar No. 54856)
Aislinn R. Klos (N.C. Bar No. 58309)
301 Fayetteville Street, Suite 1400
Raleigh, NC 27601
Tel: 919.828.0564
Fax: 919.834.4564
Email: stevecarey@parkerpoe.com
corrihopkins@parkerpoe.com
aislinnklos@parkerpoe.com

COOLEY LLP
Sanya Sukduang (Special Appearance forthcoming)
Jonathan Davies (Special Appearance forthcoming)
Phillip E. Morton (Special Appearance forthcoming)
Bonnie Fletcher-Price (Special Appearance forthcoming)
John A. Habibi (Special Appearance forthcoming)
Rachel Preston (Special Appearance forthcoming)
Jordan Landers (Special Appearance forthcoming)
1299 Pennsylvania Avenue, NW, Suite 700
Washington, DC 20004-2400
Tel: 202.842.7800
Email: ssukduang@cooley.com
jdavies@cooley.com
pmorton@cooley.com
bfletcherprice@cooley.com
jhabibi@cooley.com
rpreston@cooley.com
jlanders@cooley.com

Daniel Knauss (Special Appearance forthcoming)
Lauren Strosnick (Special Appearance forthcoming)
Kyung Taeck Minn (Special Appearance forthcoming)
3175 Hanover Street
Palo Alto, CA 94304-1130
Tel: 650.843.5000
Email: dknauss@cooley.com
lstrosnick@cooley.com
rminn@cooley.com

Attorneys for Plaintiff Liquidia Technologies, Inc